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TITLE:	MULTI-PATH TRANSTHORACIC DEFIBRILLATION AND CARDIOVERSION
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MULTI-PATH TRANSTHORACIC DEFIBRILLATION AND CARDIOVERSION

TECHNICAL FIELD

This invention relates to transthoracic defibrillation and cardioversion (i.e., defibrillation or cardioversion performed using electrodes external to the thoracic cavity).

BACKGROUND

Normally, electrochemical activity within a human heart causes the organ's muscle fibers to contract and relax in a synchronized manner. This synchronized action of the heart's musculature results in the effective pumping of blood from the ventricles to the body's vital organs. In the case of ventricular fibrillation (VF), however, abnormal electrical activity within the heart causes the individual muscle fibers to contract in an unsynchronized and chaotic way. As a result of this loss of synchronization, the heart loses its ability to effectively pump blood. Defibrillators produce a large current pulse that disrupts the chaotic electrical activity of the heart associated with ventricular fibrillation and provides the heart's electrochemical system with the opportunity to re-synchronize itself. Once organized electrical activity is restored, synchronized muscle contractions usually follow, leading to the restoration of effective cardiac pumping.

First described in humans in 1956, transthoracic defibrillation has become the primary therapy for cardiac arrest, ventricular tachycardia (VT), and atrial fibrillation (AF). Monophasic waveforms dominated until 1996, when the first biphasic waveform became available for clinical use. Attempts have also been made to use multiple electrode systems to improve defibrillation efficacy. While biphasic waveforms and multiple-electrode systems have shown improved efficacy relative to monophasic defibrillation, there is still significant room for improvement: shock success rate for ventricular fibrillation (VF) remains less than 70% even with the most recent biphasic technology.

Cardiac fibrillation and defibrillation are still poorly understood and several hypotheses have been promulgated to explain the mechanisms of defibrillation. The concept termed the critical mass hypothesis posits that a defibrillation shock is successful because it extinguishes activation fronts within a critical mass of muscle by depolarizing all non-refractory tissue within a critical mass. The upper limit of vulnerability (ULV) theory hypothesizes that a shock will be successful when, in addition to terminating ventricular fibrillation (VF) wavefronts by prolonging refractoriness in the myocardium ahead of the wavefront, the shock also must not

initiate new fibrillation-causing wavefronts at the border of the shock-depolarized region. A shock may be of sufficient intensity to depolarize the myocardium but not be of high enough intensity to prevent new activation fronts, thus resulting in a failed defibrillation attempt. The critical point hypothesis, related to the ULV theory, states that a shock must not create a critical point where a critical voltage gradient intersects with a critical point of refractoriness. These critical points are the initiation points of refibrillation. The "extension of refractoriness" theory states that the shock-induced depolarization of the fibrillating cardiac tissue extends the period of refractoriness to incoming VF wavefronts and as a result terminates VF. Other theories, related to the ULV hypothesis are "progressive depolarization" and "propagated graded (progressive) response cellular depolarization hypothesis".

The theory of Virtual Electrode Polarization (VEP) describes the phenomena by which, because of current flow within a partially conductive medium (the myocardium) contained within another partially conductive medium (blood of the cardiac chambers, lungs, interstitial fluids and other organs within the thoracic cavity), myocardial polarization during defibrillation is characterized by the simultaneous presence of positive and negative areas of polarization adjacent to each other. "Phase Singularity" as defined within the context of VEP is a critical point that is surrounded by positively polarized (equivalent to "depolarized" in the conventional electrophysiology nomenclature), non-polarized and negatively polarized (equivalent to "hyperpolarized") areas. These phase singularities are the source of re-initiation of fibrillation. Post shock excitations initiate in the non-polarized regions between the positively and negatively polarized areas through a process termed "break excitation." The break excitations propagate through the shock-induced non-polarized regions termed "excitable gaps", and if the positively polarized regions have recovered excitability, then a re-entrant circuit at which fibrillation may initiate is formed. The upper limit of vulnerability (ULV) is attained when the areal extent of the excitable gaps is sufficiently minimized, or the shock induced voltage gradient is sufficient to cause rapid propagation of the excitation in the excitable gap, or the extension of refractoriness is sufficient to prevent further advance of the break excitations into the depolarized tissue. With biphasic defibrillation, the second phase of the shock tends to nullify the VEP effect by depolarizing the negatively polarized tissue. Since less energy is needed to depolarize repolarized tissue than further depolarize already depolarized tissue, effective biphasic defibrillation achieves nearly complete depolarization of the myocardium by reversing the

negative polarization while maintaining the positive polarization. There remain, however, excitable gaps with biphasic waveforms, albeit reduced in scope relative to monophasic waveforms.

Theoretical approaches to stimulation employing current summation of multiple current sources have been used in the past to produce in the overlap region an additive current or integrated myocardial response sufficient to cause stimulation or defibrillation while the singular current vectors would not. The approach does not address the issue that insufficiently stimulated tissue may remain in the excitable gap that may result in refibrillation.

The concept of current equalization has been promulgated as a means of understanding stimulation. The general approach is to equalize the current distribution across the heart and concentrate the current in the muscular areas of the heart. This approach does not address the generation of the excitable gap, which will still be present. As understood within the context of the VEP effect, uniform current distributions still result in an excitable gap. In fact, a uniform current distribution is not an especially relevant concept within the context of a physiological system such as that of the human thorax where conductances of the organs, muscle, fluids and bone may vary by a factor of 100. Within such a system, current distributions will not be uniform. Even in a simplified, two-conductance system, an applied uniform field will result in a non-uniform current distribution due to the difference in conductances.

The technique of superposed, multiple vector physiologic tissue stimulation has been employed as early as 1948 by Nemec, as disclosed in U.S. Patent No. 2,622,601, in which a nerve or muscle stimulator is described employing two stimulation waveform generators with multiple sets of electrode. Each waveform is an alternating current electrical signal with the difference between the two frequencies set to 1 – 100 Hz. In the areas of tissue that are exposed to currents from both sources – the regions of current superposition – a beat frequency equal to the frequency difference will be generated that is capable of stimulating the physiological tissue. U.S. Patent No. 3,774,620 added the concept of superposition of two or more AC currents that by themselves have no stimulative effect, the currents differing from each other by a low value, with an optimum interference in the treatment area. Similar methods were employed in U.S. Patent Nos. 3,774,620, 3,895,639, 4,023,574, and 4,440,121. In these and much of the subsequent art, the regions of interest were those areas where the current from the multiple sources overlapped. The summation current in the overlap region would result in a beat

frequency or additive current, which would be sufficient to cause stimulation while the singular current vectors would not.

The earliest cardioverters and defibrillators generated either a single burst of alternating current or a single pulse for application to the heart to cause cardioversion or defibrillation. However, the use of multiple pulses to accomplish cardioversion or defibrillation has also been extensively researched. U.S. Patent No. 3,605,754 discloses an early double pulse heart defibrillator employing two capacitors that are successively discharged between a single pair of electrodes. Multiple-electrode systems have been employed for implantable pacemakers and defibrillators. For example, sequential pulse multiple electrode systems are disclosed in U.S. Patent Nos. 4,291,699, 4,641,656, 4,708,145, 4,727,877 4,932,407, and 5,107,834. Sequential-pulse systems operate based on the assumption that sequential defibrillation pulses, delivered between differing electrode pairs have an integrative effect, due to the non-linear action potential response of cardiac tissue, such that the overall energy requirements to achieve defibrillation are less than the energy levels required to accomplish defibrillation using a single pair of electrodes. An alternative approach to multiple-electrode, sequential-pulse defibrillation is disclosed in U.S. Patent No. 4,641,656. One electrode pair may include a right ventricular electrode and a coronary sinus electrode, and the second electrode pair may include a right ventricular electrode and a subcutaneous patch electrode, with the right ventricular electrode serving as a common electrode to both electrode pairs. An alternative multiple-electrode, simultaneous-pulse system is disclosed in U.S. Patent No. 4,953,551, employing right ventricular, superior vena cava and subcutaneous patch electrodes. U.S. Patent No. 4,953,551 discloses simultaneous delivery of pulses between the superior vena cava and the right ventricle and between the right ventricle and a subcutaneous electrode. In U.S. Patent No. 5,163,427, two capacitor banks are provided which are simultaneously charged and then successfully or simultaneously discharged between different pairs of electrodes.

French Patent No. 2,257,312 discloses sequential pulse defibrillators employing multiple electrodes arranged in and around the heart. In that disclosure, alternating current (AC) defibrillation pulses are sequentially delivered such that each successively activated electrode pair defines a pulse vector, and such that the pulse vectors scan in a rotational fashion through the heart tissue. Pulses are delivered immediately following one another, or may overlap one another for some unspecified period. U.S. Patent No. 5,324,309 describes overlapping dual

pathway pulses where there is an intermediate current vector during the overlap period. U.S. Patent No. 5,766,226 describes a similar configuration in which the intermediate current vector changes direction and is made to cycle back and forth during the shock pulse. A similar configuration is described in U.S. Patent No. 5,800,465. U.S. Patent No. 5,330,506 describes a multi-pathway pacing method where each individual path is a subthreshold stimulus while the current level in the region of superposition is suprathreshold. The current vector in the region of superposition can be steered by varying the timing of the individual pulse onsets. U.S. Patent No. 5,431,688 describes a multi-electrode, focused waveform, with interposed pulse trains. These techniques have similar deficits in that, while they are able to reduce the excitable gap to some extent via the rotating vector produced by the overlapping of the currents, regions of excitable gap will remain that can still trigger refibrillation.

U.S. Patent No. 6,148,233 describes a multi-contact electrode composed of multiple small active areas, each active area of a size too small to defibrillate. Each active area is connected to the same current source. Division of the electrode into plural active areas is intended to provide a means of reducing skin sensitization from long-term wear of the electrodes.

SUMMARY

In a first aspect, the invention features a transthoracic defibrillator for external defibrillation, the defibrillator comprising three or more electrodes configured to be attached to the thorax of a patient to establish at least two electrical paths across the thoracic cavity and through the heart of the patient, cables to connect the three or more electrodes to a defibrillator circuit contained in a defibrillator housing, wherein the defibrillator circuit has the capability to deliver a different defibrillation waveform across each of the at least two electrical paths.

Preferred implementations of this aspect of the invention may incorporate one or more of the following. The different defibrillation waveforms may differ in at least one waveform parameter. The defibrillator circuit may have the capability to deliver the same defibrillation waveform across each of the at least two electrical, paths. The defibrillator circuit may include a processing unit for determining an transthoracic impedance distribution and for selecting the waveform parameter of the at least two electrical paths based on the transthoracic impedance distribution. The transthoracic impedance distribution may be two dimensional. The transthoracic impedance distribution may be determined by measuring impedances between

locations on the thorax. Measuring impedances between locations on the thorax may comprise measuring impedances between the electrodes. The transthoracic impedance distribution may be measured using electrical impedance tomography (EIT). The transthoracic impedance distribution may be measured using an imaging technique to determine positions of tissue regions, and computing the transthoracic impedance distribution from the positions of tissue regions and resistivities of the tissues. The imaging technique may comprise ultrasound imaging. The imaging technique may employ at least one transducer element integrated into a defibrillation pad supporting at least one of the electrodes. At least one parameter of each waveform may be one of tilt, duration, current, or voltage. The waveforms may be biphasic. The waveforms may be monophasic. The waveforms may be multiphasic. The waveforms may be interlaced. At least one parameter of each waveform may be one of tilt, duration, current, voltage, first phase duration, second phase duration, first phase average current. The waveforms across different electrical paths may be overlapping in time by at least 1 millisecond but by less than 80 percent of the duration of the shortest of the waveforms. The waveforms across different electrical paths may be delivered simultaneously. The waveforms across different electrical paths may be delivered sequentially without overlapping in time. At least one waveform parameter of each waveform may be adjusted to achieve substantially the same defibrillation efficacy for each electrical path. At least one waveform parameter of each waveform may be adjusted to achieve a selected current density distribution at the heart. At least one waveform parameter of each waveform may be adjusted to make the current density distribution at the heart more uniform than would be the case if the waveform parameter were the same for each of the electrical paths. The current density may be either peak or average current density. At least two electrodes positioned on the same side of the thorax may be combined into a unitary electrode pad that is adhered to and removed from the patient as one unit. There may be at least four electrodes, two on each side of the thorax, and two electrodes on each side of the thorax may each be combined into a unitary electrode pad that is adhered to and removed from the patient as one unit. The area of each of the electrodes through which the waveforms are delivered may be less than 70 percent of the projected area of the heart, and the sum of the areas of the electrodes on the same side of the thoracic cavity may be greater than 80 percent of the projected area of the heart. The determination of a transthoracic impedance distribution may occur at the time of or just prior to delivery of the defibrillation waveforms.

In a second aspect, the invention features a method of external electromagnetic stimulation of the interior of the body, the method comprising applying three or more electrodes to the exterior of the patient to establish at least two electrical paths across the interior of the patient, determining impedance information representative of an impedance distribution across the interior of the body, delivering an electromagnetic waveform across each of the at least two electrical paths, wherein at least one parameter of the waveform is selected using the impedance information to produce a selected current density distribution at one or more locations within the interior of the body.

Preferred implementations of this aspect of the invention may incorporate one or more of the following. The electromagnetic stimulation may be for defibrillation or cardioversion of the heart, the impedance distribution may be across the thorax, and the current density distribution may be at the heart. Determining impedance information may comprise electrical impedance tomography (EIT). Determining the impedance information may comprise imaging the body to determine positions of tissue regions, and computing the transthoracic impedance distribution from the positions of tissue regions and resistivities of the tissues. Imaging may comprise ultrasound imaging.

In a third aspect, the invention features a method of performing transthoracic defibrillation, comprising attaching three or more electrodes to the thorax of a patient to establish a plurality of electrical paths across the thoracic cavity and through the heart of the patient, and delivering a defibrillation waveform across each of at least two of the electrical paths, wherein the area of each of the electrodes through which the waveforms are delivered is less than 70 percent of the projected area of the heart, and the sum of the areas of the electrodes on the same side of the thoracic cavity is greater than 80 percent of the projected area of the heart.

Preferred implementations of this aspect of the invention may incorporate one or more of the following. The invention further comprises measuring an electrical, electrocardiographic, physiological, or anatomical parameter of the patient, and delivering defibrillation waveforms that under at least some circumstances may be different for different electrical paths, with at least one parameter of each waveform being dependent on the measured parameter. Measuring may comprise determining a transthoracic impedance distribution. The area of each of the electrodes through which the waveforms are delivered may be less than 60 percent of the projected area of the heart. The area of each of the electrodes through which the waveforms are delivered may be

less than 50 percent of the projected area of the heart. The sum of the areas of the electrodes on the same side of the thoracic cavity may be greater than 90 percent of the projected area of the heart. The sum of the areas of the electrodes on the same side of the thoracic cavity may be greater than 100 percent of the projected area of the heart. The electrodes may be positioned in anterior and posterior locations, so that the electrical paths extend between the anterior and the posterior of the patient's thorax. The electrodes may be positioned at lateral locations, so that the electrical paths extend between left and right sides of the patient's thorax. The waveforms may be multiphasic. The waveforms may be monophasic. At least two of the electrodes may be combined in one unitary electrode pad that is applied and removed from a patient as a unit. There may be a seam line between areas of the pad in which electrodes are supported, with the seam line being constructed so that the pad can be folded without creasing the areas in which electrodes are supported. There may be a multiplicity of electrodes arranged on the unitary electrode pad. The multiplicity of electrodes may be arranged to increase packing density. The electrodes may be arranged in the form of a polygon tessellation. The tessellation may be a regular tessellation comprising regular polyhedra symmetrically tiling a plane. The polyhedra may be one of a triangle, square, or hexagon.

In a fourth aspect, the invention features a method of performing transthoracic defibrillation, comprising attaching three or more electrodes to the thorax of a patient to establish at least two electrical paths across the thoracic cavity and through the heart of the patient, delivering a biphasic or multiphasic defibrillation waveform across each of the at least two electrical paths, wherein under at least some circumstances the multiphasic waveforms delivered are different for the at least two electrical paths.

Preferred implementations of this aspect of the invention may incorporate one or more of the following. The invention further comprises determining a transthoracic impedance distribution across the at least two electrical paths, and delivering the biphasic or multiphasic waveforms with at least one parameter of each multiphasic waveform being dependent on the transthoracic impedance distribution. There may be two pairs of electrodes, with one electrode of each pair located on generally opposite surfaces of the thorax. One electrode of each pair may be located on the anterior and the posterior surfaces of the thorax. The invention further comprises a pair of bridge circuits, one bridge circuit for generating each of the biphasic or multiphasic waveforms. Te biphasic or multiphasic waveforms may be delivered so as to

overlap in time. The biphasic or multiphasic waveforms may be simultaneous. The biphasic or multiphasic waveforms may be sequential.

In a fifth aspect, the invention features a defibrillation electrode comprising a first electrical wire for conveying a defibrillation pulse to or from the electrode, a metallic layer connected to the electrical cable, a conductive, skin-contacting layer for conveying the pulse from the metallic layer to the skin, an ultrasound sensor, and a second electrical wire for connecting the ultrasound sensor to an ultrasound imaging circuit.

In a sixth aspect, the invention features a method of performing transthoracic defibrillation, comprising attaching three or more electrodes to the thorax of a patient to establish a plurality of electrical paths across the thoracic cavity and through the heart of the patient, using at least two different defibrillation circuits to generate at least two generally different defibrillation waveforms, delivering one of the at least two different defibrillation waveforms across each of the at least two electrical paths, and synchronizing delivery of the at least two defibrillation waveforms by communications between the at least two different defibrillation circuits.

Preferred implementations of this aspect of the invention may incorporate one or more of the following. The defibrillation circuits may each comprise a processor, an energy delivery circuit, and a switching circuit. The defibrillation circuits may be contained in separate housings, and the communications occurs between the housings. The switching circuit may be capable of generating a biphasic or multiphasic defibrillation waveform. The synchronizing delivering may include analog communication between the defibrillation circuits. The synchronizing delivering may include digital communication between the defibrillation circuits. The defibrillation circuits may be contained in separate housings. The defibrillation waveforms may deliver primarily electrical current. The defibrillation waveforms may deliver primarily a magnetic field. There may be an energy delivery circuit comprising one or more capacitors, a charging circuit for charging the one or more capacitors, and a switching circuit coupled to the one or more capacitors. An additional switch may be provided for decoupling the capacitor from the charging circuit prior to delivery of the waveform. The switching circuit may be configured as a Class D amplifier. The switching circuit may be configured as a Class B amplifier. The switching circuit may be configured as a Class AB amplifier. The invention further comprises delivering diaphragmatic stimulation. At least one diaphragmatic electrode may be provided for

delivering the diaphragmatic stimulation. At least two of the defibrillation electrodes and at least one diaphragmatic electrode may be combined in one unitary electrode pad that is applied and removed from a patient as a unit. A device for delivering chest compressions may be provided. The device for delivering chest compressions may comprise a compression band surrounding the thorax. The device for delivering chest compressions may comprise a piston-driven device. A physiological parameter may be measured, and a prediction of defibrillation success based on analysis of the measured physiological parameter, and a coordinated delivery of defibrillation and chest compressions may be provided based on the prediction. The coordinated delivery of defibrillation and chest compressions may be manual, advisory, semi-automated, or fully automated. Diaphragmatic stimulation for assisted breathing may also be provided. Cardiac pacing may also be provided.

Among the many advantages of the invention (some of which may be achieved only in some of its various aspects and implementations) are that the invention can provide a transthoracic cardioversion/defibrillation system that results in reduced areal extent and effects of the excitable gap during defibrillation and provides improved efficacies relative to prior art. In some implementations, the excitable gap areal extant is reduced by increasing the combined area of the electrodes on each side of the thorax (e.g., making the combined area approximately equal to or larger than the area of the heart projected onto those electrodes). Because the transthoracic impedance varies considerably across the surface of the chest, affected by the bone, skeletal muscle and cartilage of the sternum and ribs and the disparate conductances of the myocardium, blood and lung, some implementations of the invention are capable of adjusting at least one of the parameters of the waveforms such as duration, waveform shape or amplitude based on a determination of the transthoracic impedance distribution. Such a determination might be as simple as an impedance measurement between the electrodes of the electrode pair, but might also include electrical impedance tomography, ultrasonic imaging or other imaging method to determine more accurate locations of the heart, lungs and skeleton. In some implementations, the variation in transthoracic impedance may be addressed by configuring the power sources delivering waveforms as independent current sources with the current set to a desired value across a range of physiological impedances.

Conductances at the body surface do not vary nearly as much as those of the internal organs, fluids, muscle and bone. Thus, the typical prior art single-point impedance measurement

(e.g., at the body surface using the same electrodes that deliver the defibrillation current) is unable to estimate the impedance distribution within the thoracic cavity. Waveform shape, amplitude, or duration has been varied depending on such single-point impedance measurements, and this approach can have an impact on the efficacy of the defibrillation pulse, but its effect is limited by the fact that it does nothing to alter the current distribution in and around the heart. In preferred implementations, the invention determines the impedance (resistivity) distribution of the thorax in at least two dimensions, and uses the impedance distribution to determine the waveform parameters for each electrical path (current vector). E.g., the amplitude of the defibrillation pulse for each electrode pair can be independently adjusted to achieve a desired current distribution in and around the myocardium. Using such implementations of the invention, the current actually delivered to the organs themselves can be controlled at the surface of the body on as fine a level of detail as determined by the number, location and size of the electrodes located on the body surface.

Depending on the particular implementation, the invention is capable of improving the performance of any of the known types of defibrillation waveforms: monophasic, biphasic, or multiphasic. Preferably, the waveforms of the individual vectors are synchronized, but the invention is also capable of improving the performance of sequentially pulsed, multi-electrode defibrillation systems.

Some implementations of the invention measure the electrical, electrocardiographic, physiological, or anatomical parameters of the patient along an axis substantially similar to the axis of an electrode pair at the time of or just prior to defibrillation, and use the measurements to control the waveform parameters to improve efficacy.

Some implementations of the invention have current pathways that are independently measurable and controllable, but in other, simpler implementations, a waveform parameter of at least one of the current pathways is controlled as a function of the electrical, electrocardiographic, physiological or anatomical parameters of the patient.

Some implementations of the invention provide for synchronizing in a master/slave fashion multiple defibrillators that individually can function as standard monophasic or biphasic defibrillators.

The multiple electrodes may be implemented as active electrode areas integrated into a single pad, with one pad applied to each side of the thorax, thereby achieving a two-pad, easy-to-

use system. The integrated pads may include anatomical markings such as correctly placed drawings of the sternum, sternal notch, or nipples to provide the clinician with the ability to more accurately place the electrodes on the patient. The electrodes may include sensors such as ultrasonic imaging, impedance, pulse oximetry, end-tidal carbon dioxide, blood pressure, velocity sensing, acceleration sensors.

The active electrode areas of the integrated pad may be configured to provide optimum spacing by placing them in a close-packed hexagonal, rectangular, or concentric configuration or other tessellations.

Other features and advantages of the invention will be apparent from the drawings, detailed description, and claims.

DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic of the circuitry for a biphasic defibrillator implementation.

FIG. 2 is a block diagram of the implementation of FIG. 1.

FIG. 3 is a plot of a biphasic waveform produced by the implementation of FIG. 1.

FIG. 4 is a cross section of the thorax at the elevation of the heart used in finite element modeling showing the finite element mesh decomposition.

FIG. 5a is a simplified version of FIG. 4 with electrode locations and coordinate axes and plans.

FIG. 5b is a simplified version of FIG. 4 showing a preferred set of electrode locations.

FIG. 5c is a simplified version of FIG. 4 showing an alternative set of electrode locations.

FIG. 5d is a simplified version of FIG. 4 showing a further alternative set of electrode locations.

FIG. 6 shows an isoconductance plot of the anterior thorax.

FIG. 7 shows the placement of the anterior electrodes of FIG. 5b relative to the heart.

FIGS. 8a and 8b show the placement of the electrodes of FIG. 5b.

FIG. 9 shows an example of an annular electrode configuration.

FIG. 10 shows examples of electrodes arranged in regular tessellations.

FIG. 11 shows examples of electrodes arranged in semi-regular tessellations.

FIG. 12 shows examples of electrodes arranged in demi-regular tessellations.

FIG. 13 shows a simulation of the effects on the heart due to a monophasic defibrillation pulse as modeled using the Virtual Electrode Theory.

FIG. 14a, 14b depict, diagrammatically, what occurs when the area of the electrodes is varied.

FIG. 15 is an electrical schematic of an H-Bridge Class D configuration circuit.

FIG. 16 is an electrical schematic of circuitry driving an H-bridge Class D configuration circuit.

FIG. 17 are waveforms produced by the H-bridge Class D configuration circuit.

FIG. 18 is a plan view of an integrated defibrillation pad including an ultrasonic gel window for application of an ultrasonic probe.

FIG. 19 is a block diagram of an implementation with dual defibrillators.

FIG. 20 is a plan view of two integrated defibrillation electrode pads, electrically connected with a common connector in a dual defibrillator system.

FIG. 21 is a perspective view of a patient to which an integrated defibrillation pad with anatomical markings has been applied.

FIG. 22 is a block diagram of an integrated resuscitation system implementation.

FIG. 23 is a decision flowchart for the integrated resuscitation system.

DETAILED DESCRIPTION

There are a great many possible implementations of the invention, too many to describe herein. Some possible implementations that are presently preferred are described below. It cannot be emphasized too strongly, however, that these are descriptions of implementations of the invention, and not descriptions of the invention, which is not limited to the detailed implementations described in this section but is described in broader terms in the claims.

One implementation of the invention is depicted in FIG. 1. In the preferred embodiment, the defibrillation waveform delivered to the patient is a biphasic or multiphasic waveform as described in U.S. Patent No. 6,096,063. As described in that patent, the electromagnetic (EM) energy delivery means **1** is comprised of storage capacitors **2, 3** which are charged to a therapeutically effective voltage by a charging circuit **4** under control of the processing means **5** while relays **6, 7, 8** and **9** and the H-Bridges **10, 11** are open. As a means of reducing both size and cost, charging circuit **4** is used to charge both storage capacitors **2, 3** simultaneously. The

first electrode pair **1** and the second electrode pair **2** are self adhesive pads, such as STAT-PADZ (ZOLL Medical Chelmsford MA), that are adhered to the patient's chest **3**, shown in cross-section in FIG. 1.

Upon determination by processing means **5**, using any existing methods known to those skilled in the art, of the appropriate time to deliver the defibrillation energy to the patient, relay switches **12, 13, 14** and **15** are opened, and relay switches **6, 7, 8** and **9** are closed. Then, the electronic switches **16, 17, 18,** and **19** of H-bridge **10** and **24, 25, 26,** and **27** of H-bridge **11** are closed to allow electric current to pass through the patient's body in one direction , after which electronic switches **16, 17, 18,** and **19** of H-bridge **10** and **24, 25, 26,** and **27** of H-bridge **11** are opened and **20, 21, 22,** and **23** of H-bridge **10** and **28, 29, 30** and **31** of H-bridge **11** are closed to allow the electric current to pass through the patient's body in the other direction. Relay switches **12, 13, 14** and **15** are combined in double-pole double-throw configuration (DPDT) to reduce size and cost. DPDT relay **12, 13** serves the purpose of isolating the current sources for the electrode pairs during discharge. Electronic switches **16-31** are controlled by signals from respective opto-isolators, which are, in turn, controlled by signals from the processing means **5**. As shown in FIG. 2, processing means **5** is preferably a microprocessor, such as a Hitachi SH-3 **40** combined with a read only memory device (ROM) **41**, random access memory (RAM) **42**, Clock **43**, real time clock **44**, analog-to-digital **45** and digital-to-analog **46** converters, power supply **47**, reset circuit **48**, general purpose input/output **49**, and user interface in the form of a display **49** and input keys **50** and other circuitry known to those skilled in the art. A measurement means **52** is provided for measurement of electrical, electrocardiographic, physiological or anatomical parameters of the patient, the processing means **5** controlling the waveform parameters of at least one of the discharge pathways based on this measurement. Relay switches **6, 7, 8,** and **9** which are also controlled by the processing means **5**, isolate patient **3** from leakage currents of H-bridge switches **16-31** which may be about 500 microamperes.

Resistive circuits **55, 56** that include series-connected resistors **57, 58, 59** and **60, 61, 62,** respectively, are provided in the current path, each of the resistors being connected in parallel with shorting switch **63-68** controlled by processing means **5**. The resistors are preferably of unequal value and stepped in a binary sequence such that with the various combinations of series resistance values, there are 2^n different combinations, where n is the number of resistors. Immediately prior to delivering the therapeutic defibrillation energy a smaller amplitude

"sensing" pulse is delivered by closing H-bridge switches **16-19** and **24-27** and the resistor shorting switches **63-68** are all open so that current passes through the resistors in series. The current sensing transformers **69** and **70** sense the current that passes through the patient through their respective electrode pairs **1a, 1b, 2a** and **2b**, from which the processing means **5** determines the resistance of the patient **3**.

The initial sensing pulse is integral with, i.e., immediately followed by, a biphasic defibrillation waveform, and no re-charging of storage capacitor occurs between the initial sensing pulse and the biphasic defibrillation waveform. If the patient resistance sensed during the initial sensing pulse is low, all of the resistor-shorting switches **63-68** are left open at the end of the sensing pulse so that all of the resistors **57-62** remain in the current path (the resistors are then successively shorted out during the positive phase of the biphasic defibrillation waveform in the manner described below in order to approximate a rectilinear positive phase). Thus, the current at the beginning of the positive first phase of the biphasic defibrillation waveform is the same as the current during sensing pulse. If the patient resistance sensed during the sensing pulse is high, some or all of the resistor-shorting switches **63-68** are closed at the end of the sensing Pulse, thereby shorting out some or all of the resistors.

Thus, immediately after the sensing pulse, the biphasic defibrillation waveform has an initial discharge current that is controlled by microprocessor **46,** based on the patient impedance sensed by current-sensing transformer **69, 70**. The current level of the sensing pulse is always at least 50 percent of the current level at the beginning of positive first phase, and the sensing pulse, like the defibrillation pulse, is of course a direct-current pulse.

By appropriately selecting the number of resistors that remain in the current path, the processing means reduces (but does not eliminate) the dependence of peak discharge current on patient impedance, for a given amount of charge stored by the charge storage device. For a patient impedance of 15 ohms, the peak current is about 25 amperes, whereas for a patient impedance of 125 ohms, the peak current is about 12.5 amperes (a typical patient is about 75 ohms.)

During the positive phase of the biphasic waveform, some or all of the resistors **57-62** that remain in series with the patient **3** are successively shorted out. Every time one of the resistors is shorted out, an upward jump in current occurs in the waveform, thereby resulting in the sawtooth ripple shown in the waveform of FIG. **3.** The ripple tends to be greatest at the end

of the rectilinear phase because the time constant of decay (RC) is shorter at the end of the phase than at the beginning of the phase. Of course, if all of the resistors have already been shorted out immediately after the end of the sensing pulse, the positive phase of the biphasic waveform simply decays exponentially until the waveform switches to the negative phase.

As is shown in **FIG. 3,** at the end of the positive phase, the current waveform decreases through a series of rapid steps from the end of the positive phase to the beginning of negative phase, one of the steps being at the zero crossing. Processing means **5** accomplishes this by (1) successively increasing the resistance of resistive circuit 55, 56 in fixed increments through manipulation of resistor-shorting switches **57-62,** then (2) opening all of the switches in H-bridges **10-11** to bring the current waveform down to the zero crossing, then (3) reversing the polarity of the current waveform by closing the H-bridge switches that had previously been open in the positive phase of the current waveform, and then (4) successively decreasing the resistance of resistance circuit **55, 56** in fixed increments through manipulation of resistor-shorting switches **57-62** until the resistance of resistance circuit **55, 56** is the same as it at the end of the positive phase.

In one implementation a variable resistor **71, 72** is provided in series with the other resistors **57-62** to reduce the sawtooth ripple. Every time one of the fixed-value resistors **57-62** is shorted out, the resistance of variable resistors **71, 72** automatically jumps to a high value and then decreases until the next fixed-value resistor is shorted out. This tends, to some extent, to smooth out the height of the sawtooth ripple from about 3 amps to about 0.1 to 0.2 amps, and reduces the need for smaller increments of the fixed-value (i.e., it reduces the need for additional fixed-value resistor stages).

A cross-sectional view of the human thorax is shown in **FIG. 4**. Each of the constituent tissues are subdivided into cells for use in finite element simulations of the fields and currents generated by defibrillation pulses. Electrode pairs **1a, 1b, 2a,** and **2b** are also depicted in the figure. **FIG. 5a - d** depicts a simplified version of the cross section of **FIG 4**. A line is defined in the figure, the Cardiac Center of Mass (CCOM) line **75**, which runs through the CCOM point **76** and is parallel to the patient's back. In preferred implementations, at least one, and preferably two, electrodes are located posterior to the CCOM line. Additionally, the midpoint/COM (MCOM) line **77** is the line defined by midpoint of the lateral extent (MLE) of the posterior electrode or electrodes **78, 79** and the CCOM point **76**. The electrode plane **81**, is defined by the

plane resulting in the least mean squared error distance to the centroids **82** of the electrodes distal **84** to the MLE **78**. There is further defined a Projected Cardiac Area (PCA), that is the area in the electrode plane **81** of the shape formed by the intersection of the electrode plane **81** with the locus of lines **80** parallel to the MCOM line **77** and tangent to the surface of the heart **83**. The area, shape and position of the electrodes are such that the area of each individual electrode is less than 70% of the PCA and the sum of the areas of the electrodes distal **84** to the MLE **78** is greater than 80%, and preferably 100%, of the PCA.

In a preferred implementation, the electrodes are positioned as shown in FIGS. 5b, 7, 8a and 8b. FIG. 7 shows the relative location of the electrodes **1a, 2a** and the thoracic cage and the heart **4**. FIG 8a and 8b show the electrode placement on a typical patient. FIG 5c depicts a lateral placement of the electrode pairs. In another embodiment, the electrodes may be configured as concentric, as shown in FIG 9. The electrodes may also be placed so that the current pathways are essentially parallel, as shown in FIG 5d (in which the locations of electrodes 1b and 2b have been reversed from FIG. 5b).

The conductances of the various tissues as shown in FIG. 4 are approximately as follows:

Tissue type	Conductivity (ohms-cm)
Skin	3.4
Blood	6.5
Lung	0.7
Skeletal Muscle	1.5 (transverse) 4.2 (longitudinal)
Fat	0.5
Cardiac Muscle	7.6
Bone	0.06

Conductivities of the various tissues can vary by as much as a factor of 100. To accommodate this, waveform parameters of the energy delivered to each of the discharge pathways is independently controllable. For example, this may be accomplished in the just-described embodiment by providing two high voltage capacitors **2, 3** and by appropriately switching the resistors **57-62** that remain in series with the patient **3**. By appropriately selecting the number of resistors that remain in the current path, the dependence of peak discharge current

on patient impedance can be reduced (but not eliminated), for a given amount of charge stored by the charge storage device. For example, for a patient impedance of 15 ohms, the peak current is about 25 amperes, whereas for a patient impedance of 125 ohms, the peak current is about 12.5 amperes (a typical patient is about 75 ohms.)

Alternatively, independent control may also be achieved by providing only one high voltage capacitor for more than one of the electrode pairs while still providing separate resistor networks **57–59** and **60–62** for each current pathway. Another waveform parameter that may be adjusted is waveform duration, which is controllable by switch networks **10, 11**. The average first phase current can also be independently adjusted, e.g., by providing a second charging circuit **4** to charge a second group of one or more capacitors to a voltage independent from the first group of one or more capacitors. Waveform parameters for independent adjustment include, but are not limited to, tilt, duration, first phase duration, second phase duration, current, voltage, and first phase average current.

As can be seen in the isoadmittance curves shown in FIG. 6, the conductances of the internal organs, muscle and bone vary significantly, much more so than do conductances at the body surface. In a preferred implementation, electrical impedance tomography (EIT) is used to determine these internal conductances or impedances. Electrical impedance tomography (EIT) is used to determine the resistivity distribution of the thorax in at least two dimensions, and the calculated resistivity distribution is then used to determine the waveform parameters for each current vector. For example, the amplitude of the defibrillation pulse for each electrode pair can be independently adjusted to achieve the optimal current distribution in and around the myocardium. Using such a method, the current actually delivered to the organs themselves can be controlled at the surface of the body on as fine a level of detail as determined by the number, location and size of the electrodes located on the body surface.

In the most basic implementation, only three electrodes with three possible electrode pairs is sufficient to use EIT methods to determine waveform parameters. In the preferred implementation shown in FIG. 5b, four electrodes are used, for a total of six [(n-1)!] possible electrode pairs. This number is chosen for ease of implementation and cost; implementations with more electrode pairs are possible.

The EIT system is governed by Poisson's equation:

$$\nabla \cdot \rho^{-1} \nabla V = I,$$

Where V is the voltage, ρ is the resistivity distribution and I is the impressed current source distributions within the region being studied and the boundary conditions are V_0 and J_0. In the case of EIT, high frequency, low amplitude signals, e.g., 60 KHz and ~1 microampere respectively, are used. Since there are no current sources of this frequency in the body, then ρ = 0, and Poisson's equation becomes Laplace's equation:

$$\nabla \cdot \rho^{-1} \nabla V = 0$$

In the field of EIT, several types of problems are studied:

1. The "forward problem", where ρ, V_0 and J_0 are given and the goal is to determine the voltage and current distributions V and J.
2. The "inverse problem", where V and J are given and the goal is to determine ρ.
3. The "boundary value" problem where V_0 and J_0 are given and the goal is to determine ρ, V and J.

In a preferred implementation, ρ, V and J are determined using boundary value problem methods, then once ρ is determined, the optimal V_0 and J_0 are determined using a modified inverse problem where the desired V and J in and near the myocardium are given and the defibrillation waveforms for each of the electrode pairs is generated.

In general principle, the process of EIT involves injecting a current by an electrode, and the induced voltage is measured at multiple points on the body surface. In the preferred embodiment, what is termed the "multireference method" is used for configuring the current voltage pairs. (Hua P, Webster JG, Tompkins WJ 1987 Effect of the Measurement Method on Noise Handling and Image Quality of EIT Imaging, Proc. Annu. Int. Conf. IEEE Engineering in Medicine and Biology Society 9 1429 – 1430.) In the multireference method, one electrode is used as the reference electrode while the remaining electrodes are current sources with the induced voltages being measured on each electrode simultaneously while the current is being delivered. The amplitude of the current sources are individually varied and each electrode is treated as a reference lead in succession. Finite element methods are then used to convert the calculus problem ($\nabla \cdot \rho^{-1} \nabla V = 0$) into a linear algebra problem of the form $\mathbf{YV} = \mathbf{C}$, where **Y, V,**

and **C** are the conductance, voltage, and current matrices respectively. **Y, V,** and **C** are also sometimes known as the master matrix, node voltage vector, and node current vector respectively. Mesh generation is performed on the two or three-dimensional physical model with triangular or quadrilateral elements for two dimensional problems and hexahedral shapes for three-dimensional problems. Boundary conditions are then set such as at the reference node or driving electrodes for Dirichlet (known surface voltages) or Neuman (known surface currents) boundary conditions. A number of methods have been used to compute the master matrix such as Gaussian elimination or Cholesky factorization.

The Newton-Raphson algorithm may also be used for reconstruction of the resistivity distribution. The algorithm is an iterative algorithm particularly well suited to non-linear problems. The Newton-Raphson method minimizes an error termed the "objective function". Here, it is defined as the equally weighted mean square difference between the measured and estimated voltage responses:

$$\Phi(\rho) = (1/2)\,(\mathbf{V_e}(\rho) - \mathbf{V_0})^T\,(\mathbf{V_e}(\rho) - \mathbf{V_0}).$$

Using methods known to those skilled in the art, an algorithm is utilized whereby a distribution is first estimated, then the theoretical voltage response to a given current input is calculated using the finite element method. The estimated voltages are subtracted from the measured voltages to obtain the objective function. If the objective function is less than an error threshold, the estimated distribution is deemed to be an acceptable estimation. If not, the following equation is used to update the resistivity distribution:

$$\Delta\,\rho^k = -\,[\mathbf{V_e}'(\rho^k)^T\,\mathbf{V_e}'(\rho^k)]^{-1}\,\{\mathbf{V_e}'(\rho^k)^T\,[\mathbf{V_e}'(\rho^k) - \mathbf{V_0}]\}$$

This sequence is repeated until an acceptable estimation is achieved.

In a preferred implementation, a table lookup method is provided to determine the estimated voltage matrix $\mathbf{V_e}(\rho)$. The table values are based on average patient resistivity distributions and assuming correct placement of the electrode. Better accuracy can be achieved by providing anatomical markings **126** on the electrode pad as shown in FIG. 21.

Accuracy may also be improved by providing a secondary imaging method such as ultrasound to take advantage of its higher imaging resolution to calculate the positions of the internal organs relative to the electrodes. If a secondary imaging method such as ultrasound is used to determine the positions of internal tissues, EIT can be used to determine the resistivities of each tissue type.

In other implementations, an average resistivity value is determined for the tissue regions as defined by the secondary imaging method. This is accomplished by first defining a tissue region such as the lungs or myocardium by standard image processing methods. Next, the calculated resistivity distribution is overlayed onto the secondary image. All nodes of the resistivity distribution that are contained within a particular tissue region are combined together into a single resistivity measure for that tissue region. The method of combination may be an averaging, median, or other statistical or image processing method.

The optimal V_0 and J_0 are determined using a modified inverse problem where the desired V and J in and near the myocardium are given and the defibrillation waveforms for each of the electrode pairs is generated.

Improved current delivery (and impedance measurements) can be achieved by close-packing a large number of electrodes. Many arrangements of electrodes are possible. In a preferred implementation, the configuration of electrodes is determined with the assistance of the theory of tessellation. A regular tiling of polygons (in two dimensions), polyhedra (three dimensions), or polytopes (*n* dimensions) is called a tessellation. Tessellations can be specified using a Schläfli symbol. The breaking up of self-intersecting polygons into simple polygons is also called tessellation, or more properly, polygon tessellation. There are exactly three regular tessellations composed of regular polyhedra symmetrically tiling the plane, as shown in FIG. 10. Tessellations of the plane by two or more convex regular polygons such that the same polygons in the same order surround each polygon vertex are called semi-regular tessellations, or sometimes Archimedean tessellations. In the plane, there are eight such tessellations, shown in FIG. 11. There are fourteen demi-regular (or polymorph) tessellations, which are orderly compositions of the three regular and eight semi-regular tessellations. These polyhedra are shown in FIG. 12. Other demi-regular tessellations are Penrose Tilings. In three dimensions, a polyhedron that is capable of tessellating space is called a space-filling polyhedron. Examples include the cube, rhombic dodecahedron, and truncated octahedron. There is also a 16-sided

space-filler and a convex polyhedron known as the Schmitt-Conway polyhedron, which fills space only aperiodically. Space-filling polyhedron can be utilized to better fit the electrodes to the three-dimensionality of the human thorax. In the preferred embodiment, the electrode tessellation pattern is a cubic or hexagonal regular tessellation.

One possible theory to explain the improvement that some implementations of the invention may achieve in defibrillation efficacy (understanding, of course, that the invention is not limited to this theory) is as follows: As stated previously, the theory of Virtual Electrode Polarization (VEP) describes the phenomena by which, because of current flow within a partially conductive medium (the myocardium) contained within another partially conductive medium (blood of the cardiac chambers, lungs, interstitial fluids and other organs within the thoracic cavity), myocardial polarization during defibrillation is characterized by the simultaneous presence of positive and negative areas of polarization adjacent to each other. "Phase Singularity" as defined within the context of VEP is a critical point that is surrounded by positively polarized (equivalent to "depolarized" in the conventional electrophysiology nomenclature), non-polarized and negatively polarized (equivalent to "hyperpolarized") areas. These phase singularities are the source of re-initiation of fibrillation. Post shock excitations initiate in the non-polarized regions between the positively and negatively polarized areas through a process termed "break excitation." The break excitations propagate through the shock-induced non-polarized regions termed "excitable gaps", and if the positively polarized regions have recovered excitability, then a re-entrant circuit at which fibrillation may initiate is formed. With biphasic defibrillation, the second phase of the shock nullifies the VEP effect by depolarizing the negatively polarized tissue. Since less energy is needed to depolarize repolarized tissue than further depolarize already depolarized tissue, effective biphasic defibrillation achieves nearly complete depolarization of the myocardium by reversing the negative polarization while maintaining the positive polarization. There remain, however, excitable gaps even with biphasic and multiphasic waveforms, albeit reduced in scope relative to monophasic waveforms, and there still remains the potential for significant improvement of the efficacy of biphasic defibrillation waveforms.

FIG 13 shows the results of a simulation in a study by Efimov (Am J Physiol Heart Circ Physiol 2000; 279:H1055-70). The lighter grey region **90** is a region of positive polarization and the black region **91** is one of negative polarization. The white region **92** is the excitable gap

region. FIG. 14a and 14b depict, in schematic view, what occurs when the area of the electrodes is varied. As can be seen, by increasing the size of the electrodes, the contact angle, φ **93**, of the electric field lines is increased in the region of the excitable gap, thereby reducing the areal extent of the excitable gap. Reduction of the areal extent of the excitable gap, improves the chances for a successful defibrillation and reduces defibrillation thresholds.

In other implementations, the waveforms may each be composed of a sequence of pulses. The relative timing of the current vectors may be designed so that the pulse sequences are interposed with non-overlapping individual pulses.

In another implementation, resistance circuits **55, 56** are eliminated and the waveform shape, and thus also the first phase average current, is adjusted by pulse width modulating the switches in the H-bridges **10, 11**. This configuration is the Class D amplifier configuration, known to those skilled in the art of amplifier design. In its simplest form, a switch-mode amplifier consists of an H-bridge and a load as shown in FIG 15. Amplifiers are typically classified by their output stages. Of the common output-stage topologies (Classes A, B, AB, and D), Class D amplifiers exhibit the highest efficiency. A linear output stage (Class A, B, or AB) draws considerable bias current while sourcing and sinking current into a speaker making them not particularly well suited to high voltage designs. A nonlinear (Class D) output stage eliminates this bias current. In the preferred embodiment, as shown in FIG 16, the Class D amplifier consists of an input preamplifier **95** for isolating, filtering and level shifting the control voltage from the processing means **5**, a sawtooth oscillator **96**, a comparator **97**, two MOSFET drivers **98, 99**, and the H-bridge switches **100 - 103**. The comparator samples the input signal, with the oscillator frequency determining the duration of the sampling period. Thus, the oscillator frequency is an important factor in the overall performance of a Class D amplifier. As shown in FIG 17, the comparator output **104** is a pulse-width modulated (PWM) square wave that drives the H-bridge. The PWM squarewave **104** is created by a comparator whose inputs are the sawtooth (V_{RAMP}) **105** and the control signal (V_{IN}) **106**. The H-bridge then outputs the square wave differentially. For a given input level, the comparator output is a duty-cycle modulated square wave with period determined by the sawtooth frequency. The PWM square wave controls the H-bridge drivers **100 - 103**, turning opposite pairs of MOSFETs off and on, thereby reversing current to the load within a single period. The output may be filtered by

capacitor filters or inductor/capacitor filter combinations which remove high-frequency content from the H-bridge square wave output.

Alternatively, the measurement of the thoracic cavity may be carried out using an ultrasound transducer capable of imaging the heart and surrounding tissue. An ultrasound transducer may be incorporated into an integrated defibrillation pad, as shown in FIG. 18. In a preferred implementation, an opening in the center of the electrode is provided that is covered over with an ultrasonic-conducting gel **107**. The gel is a bilayer structure with a more aggressive adhesive provided on the face opposite to the patient for attaching the ultrasonic probe prior to use.

In other implementations, there may be two or more separate defibrillators, as shown in FIG 19. The first defibrillator **110** acts as the master defibrillator, while additional defibrillators **111** function as slave defibrillators whose energy is delivered synchronously with that of the master defibrillator **110**. Synchronization is provided by communication means **114**. Preferably, the communication means **114** is implemented as a simple switch. In a conventional defibrillator, the delivery of energy is initiated via the closure of a discharge switch **112** located on the front panel or on a set of defibrillation paddles. The closure of the switch initiates the defibrillation sequence under the control of processing means **5**. Charging of the high voltage capacitors on both defibrillators **110, 111** is initiated via the charge-control user inputs **115**. At the appropriate time, the clinician will press the discharge button **112**. This causes the processing means **5** on the first defibrillator **110** to close a slave discharge switch that initiates the discharge sequence on the second defibrillator **111**, at which time the first defibrillator **110** also initiates its discharge sequence. The wiring for the communication means **114** is preferably configured such that the wires are located within the same cable as the energy delivery wires, thus reducing any additional cabling. The communication means **114** may also incorporate digital communication methods which provide additional information about defibrillator status.

The defibrillator pad **123** may integrate all connections into a single connector **120** as shown in FIG. 20. The defibrillator pads may be constructed such that a seam line **121** is located between the active areas **122** of the pad **123** where the seam line **121** is of higher compliance than the active areas such that the pad **123** can be folded during storage without creasing the active areas.

In another implementation, a physiological parameter, e.g., the electrocardiograph (ECG), is measured in conjunction with the EIT image, and an estimate is made by the device of the chances for a successful defibrillation shock based analysis of ECG data. Depending on the estimate of shock success, decisions as to the proper treatment to provide the patient are made in a coordinated resuscitation effort that includes both defibrillation and chest compressions, which can be provided manually in response to prompts, or in a semi-automated or fully automated fashion. The block diagram and flow chart for such a system is shown in FIGS. 22 and 23.

One or more additional electrodes **125** may be provided for diaphragmatic stimulation (DS) and may be incorporated into the anterior electrode such that the DS Electrode (DSE) is located over the patient's diaphragm as shown in FIG. 21. Diaphragmatic stimulation induces air exchange in the lungs during cardiopulmonary resuscitation (CPR) for improved oxygenation. The return path for the stimulation current from the DSE is through one of the pre-existing electrodes. Utilizing EIT or other imaging methods, the current distribution may be adjusted to achieve optimal stimulation, as described previously in this patent. The DSE may be integrated with defibrillation and cardiac pacing to provide a coordinated resuscitation effort in an automated or semi-automated fashion. The integrated resuscitation may also incorporate a means of providing chest compressions, such as a piston-based system manufactured by Michigan Instruments (Michigan) or a constricting band system manufactured by Revivant Corp. (California). FIG. 23 shows a decision flow chart of one possible integrated resuscitation protocol.

Many other implementations of the invention other than those described above are within the invention, which is defined by the following claims. The invention applies to both defibrillation and cardioversion; in the claims, references to defibrillation should be interpreted as also encompassing cardioversion. Some implementations of the invention are broader than defibrillation and cardioversion.